IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9285

Bartle, J. June 3, 2014

Patrick J. Venetz ("Mr. Venetz" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Nancy E. Venetz, Mr. Venetz's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In April, 2012, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Robert L. Rosenthal, M.D. Based on an echocardiogram dated September 29, 2002, Dr. Rosenthal attested in Part II of claimant's Green Form that Mr. Venetz had moderate mitral regurgitation, surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™, and ventricular fibrillation or sustained ventricular tachycardia

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3. (...continued)
presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

which resulted in hemodynamic compromise.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level V benefits[5] in the amount of $987,173.[6]

In the report of claimant's September 29, 2002 echocardiogram, the reviewing cardiologist, Jacques Benisty, M.D., stated that claimant had moderate mitral regurgitation, which he measured at 34%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In May, 2012, the Trust forwarded the claim for review by Waleed N. Irani, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Irani concluded that there was no

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4. Dr. Rosenthal also attested that claimant suffered from an abnormal left atrial dimension and arrhythmias. These conditions are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level V benefits if he or she qualifies for Level III Matrix Benefits and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. See Settlement Agreement § IV.B.2.c.(5)(d). A claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Id. § IV.B.2.c.(3)(a).

6. Mr. Venetz previously received Seventh Amendment Category One Benefits in the amount of $302,245. According to the Trust, if entitled to Matrix A-1, Level V benefits, Mr. Venetz would be entitled to Matrix Benefits in the amount of $1,289,418. The amount at issue, therefore, is the difference between the Seventh Amendment Category One Benefits already paid and the Matrix A-1, Level V benefits. See Seventh Amendment § IX.A.2.

reasonable medical basis for finding that claimant's September 29, 2002 echocardiogram demonstrated moderate mitral regurgitation. Specifically, Dr. Irani explained:

> [RJA] is large due to inclusion of low velocity nonturbulent flow from pulmonary vein inflow which is color coded in deep red indicating flow of blood toward [mitral valve] in atrium. In addition the Nyquist limit is quite low at 41 cm/s which causes blooming of jet. Visually [mitral regurgitation] appears mild.[7]

The Settlement Agreement requires the payment of reduced Matrix Benefits to a claimant who is diagnosed with mild mitral regurgitation by an echocardiogram that was performed between the commencement of Diet Drug use and the end of the Screening Period.[8] See id. § IV.B.2.d.(2)(a). As the Trust does not contest claimant's entitlement to Level V benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.[9]

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7. Under the Settlement Agreement, mild mitral regurgitation is defined as "(1) either the RJA/LAA ratio is more than five percent (5%) or the mitral regurgitant jet height is greater than 1 cm from the valve orifice, and (2) the RJA/LAA ratio is less than twenty percent (20%)." Id. § I.38.

8. The Screening Period ended on January 3, 2003 for echocardiograms performed outside of the Trust's Screening Program and on July 3, 2003 for echocardiograms performed in the Trust's Screening Program. See Settlement Agreement § I.49.

9. If Mr. Venetz's supplemental claim for Level V benefits is payable only on Matrix B-1, he will not receive any additional payment because the amount to which Mr. Venetz would be entitled is less than the amount he already received under the Seventh Amendment. See Settlement Agreement § IV.C.3.; Seventh Amendment § IX.A.2.

Based on Dr. Irani's finding, the Trust issued a post-audit determination that Mr. Venetz was entitled only to Matrix B-1 benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[10] In contest, Mr. Venetz argued that the auditing cardiologist "complained about the technician's tracings and the Nyquist limit," rather than determining his "true medical condition...." In addition, claimant asserted that the auditing cardiologist's methodology for reviewing Mr. Venetz's September 29, 2002 echocardiogram was "unknown" as it was unclear whether the auditing cardiologist's opinion was based on a single frame and whether the auditing cardiologist measured specific frames.[11]

Mr. Venetz also submitted declarations from Dr. Rosenthal and Paul W. Dlabal, M.D., F.A.C.P., F.A.C.C., F.A.H.A. In his declaration, Dr. Rosenthal stated, in pertinent part:

> 5. In his report, the auditor claimed that "Regurgitant jet area (RJA) was large due to

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10. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Venetz's claim.

11. Claimant also asserted that the auditing cardiologist "either failed to review multiple loops and/or he consciously sought to suppress the evidence that was favorable to the Claimant." Claimant provided no support for this assertion.

inclusion of low velocity nonturbulent flow from pulmonary vein inflow." To the contrary, Page 20 of 53 at 7:48:43 reveals a jet area of 7.10 cm^2. The area outlined is of only turbulent flow, as demonstrated by the variation in color from pixel to pixel. Flow is drawn originating from the mitral valve well away from the pulmonary vein entry points (which are anatomically on the opposite side of the atrium) and therefore impossible to be from pulmonary vein inflow.

6. In his report, the auditor also claimed that "RJA was color coded in deep red indicating flow of blood toward [mitral valve] in atrium." However, on Page 20 of 53 at 7:48:43, there is no red color included in the jet area of 7.10 cm^2. In fact, it is specifically excluded as is apparent to the untrained observer's eye.

7. The auditor also claimed that "The Nyquist Limit was quite low at 41 cm/s which caused blooming of jet." However, the Nyquist Limit at 41 cm/sec would impact the jet area only if nonturbulent low velocity flow was outlined. On the other hand, the turbulent flow present in this case has velocity multiples above the Nyquist Limit being 500-600 cm/sec and a reduction of the Nyquist Limit from 60 cm/sec to 41 cm/sec will have minimal decrement in the area of turbulent flow and will be readily apparent at either Nyquist setting.

8. Lastly, the auditor claimed that "Visually [mitral regurgitation] appeared mild." This is also incorrect. Visually at 7:48:43, the jet area by "eye ball" fills approximately 40% of the left atrial area. Similar jets outlined on other frames also visually appear to fill greater than 20% of the left atrial area.

9. The regurgitant jets that I identified were true regurgitant jets, and they were representative of other jets that were also in the moderate range.

In his declaration, Dr. Dlabal identified five frames from the four-chamber view and two frames from the two-chamber view that he maintained demonstrated at least moderate mitral regurgitation. Dr. Dlabal further asserted, in pertinent part:

> 5. These jets were true regurgitant jets, and they were representative of other jets that were also in the moderate range.
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> 6. On average, the views showed significant [mitral regurgitation], all in the pathologic range, and have an RJA=6.8 cm sq. The [left atrium] was slightly larger than normal, measuring 5 cm in the [antero-posterior] direction. Calculated LAA, using this reference, = 19 cm sq. Therefore, the average RJA/LAA = 0.35 or 35%.
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> 8. The images that I selected did not include areas of low-velocity non-turbulent flow from pulmonary vein inflow. While some images on the disc may include areas of such flow, I carefully excluded these images from my analysis of the [mitral regurgitation] level.
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> 9. Certain images on the disc also included areas of deep red coloration, indicating inflow into the left ventricle. However, I also excluded these images from my analysis.
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> 10. The Nyquist Limit on this study is set at a somewhat low level. However, the Nyquist setting did not introduce artifact, thus the study is deemed technically satisfactory for interpretation. Accordingly, the Nyquist Limit setting in this case was a minor irrelevant issue.
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> 11. If anything, [mitral regurgitation] appeared severe in most frames, and I was being generous to measure it as moderate. Therefore, there is a reasonable medical basis to conclude that the level of [mitral regurgitation] was at least moderate.

Finally, claimant submitted the results of the Medical Review of his echocardiogram in connection with his claim for Category One Benefits under the Seventh Amendment, which indicated that he had moderate mitral regurgitation, even though the RJA/LAA ratio is listed as less than 20%.

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist. Dr. Irani submitted a declaration in which he again concluded that there was no reasonable medical basis for the attesting physician's finding that claimant's September 29, 2002 echocardiogram demonstrated moderate mitral regurgitation. Specifically, Dr. Irani stated, in pertinent part:

> Based on my review, I confirm my finding at audit that there is no reasonable medical basis for the Attesting Physician's finding that Claimant had moderate mitral regurgitation. I reviewed the entirety of Claimant's September 29, 2002 echocardiogram study, as well as at those points identified by Drs. Rosenthal and Dlabal. Only mild mitral regurgitation is present in real time. The Nyquist setting at those points identified by Drs. Rosenthal and Dlabal is very low, at 41 cm/sec, resulting in increased color signal and falsely inflated jet size to an RJA/LAA ratio of 20%: (RJA 5.4 cm2, measured by me at 07:48:43 on tape and LAA area 27.0 cm2, measured by me at 07:48:01 on tape). However, these still frames do not reflect the actual degree of mitral regurgitation and do not reasonably support a finding of moderate mitral regurgitation. These still frames reflect inflated jet size due to very low Nyquist setting resulting in increased color signal. The still frames identified by Drs. Rosenthal and Dlabal are not representative of mitral regurgitation seen in real time. Mitral regurgitation is mild in real time.

The Trust then issued a final post-audit determination, again determining that Mr. Venetz was entitled only to Matrix B-1, Level V benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On December 18, 2012, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8986 (Dec. 18, 2012).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on March 20, 2013, and claimant submitted a sur-reply dated April 3, 2013. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[12] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review

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12. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden of proving that there is a reasonable medical basis for finding that he suffered from moderate or greater mitral regurgitation on an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in the Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, claimant reasserts the arguments he made during contest. Claimant also argues that there is a reasonable medical basis for his claim because: (1) the opinion of his attesting physician is entitled to deference, and (2) multiple cardiologists adequately rebutted the findings of the auditing cardiologist because they concluded that

he had moderate mitral regurgitation.[13] In addition, claimant submitted supplemental declarations from Dr. Rosenthal and Dr. Dlabal, in which they again opine that the auditing cardiologist is incorrect and that claimant's September 29, 2002 echocardiogram reveals the presence of moderate mitral regurgitation.[14] Finally, claimant asserts that the Settlement Agreement and the Seventh Amendment to the Settlement Agreement "'guaranteed' payments if [a claimant's] condition worsened to certain points...."

The Trust counters that claimant has not established a reasonable medical basis for Dr. Rosenthal's representation that claimant had moderate mitral regurgitation between the commencement of Diet Drug use and the end of the Screening Period and that the reasonable medical basis standard does not require that deference be given to the findings of the attesting physician. In addition, the Trust contends that it and the auditing cardiologist properly interpreted the reasonable medical

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13. Claimant also notes that the auditing cardiologist calculated Mr. Venetz's level of mitral regurgitation as 20%. This ignores, however, that Dr. Irani went on to state, "However, these still frames do not reflect the actual degree of mitral regurgitation and do not reasonably support a finding of moderate mitral regurgitation."

14. Claimant asserts that Dr. Rosenthal confirmed the presence of moderate mitral regurgitation using both the vena contracta and proximal flow convergence methods and that use of these additional methods are consistent with "best practices." Dr. Dlabal, however, specifically notes that these methods are "not widely used." In any event, the Settlement Agreement requires the use of the Singh method. See Settlement Agreement § I.22.

basis standard. Finally, the Trust asserts that the Seventh Amendment does not "guarantee" claimants supplemental Matrix Benefits.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for finding that it demonstrated moderate or greater mitral regurgitation. Specifically, Dr. Vigilante stated, in pertinent part:

> I reviewed the DVD of the Claimant's September 29, 2002 echocardiogram.... There were 52 loops/images on this study. All of the usual echocardiographic views were obtained. However, this study was performed significantly below the appropriate standard of care. The Nyquist limit was inappropriately low at 41 cm per second at a depth of 16cm in the parasternal views and 41 cm per second at a depth of 19 cm in the apical views. There was significantly increased color gain noted throughout the color flow loops. This color artifact was noted throughout the study. Abnormal color speckling could be seen without the apical myocardium in the apical views documenting significantly abnormal acquisition and demonstration of color flow in the apical views.
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> Visually, the mitral valve appeared normal. The leaflets were thin and pliable. They opened and closed normally. There was no evidence of mitral valve prolapse or mitral annular calcification. Visually, there was evidence of mitral regurgitation noted. This most likely was mild. However, it was impossible to quantitate the severity of mitral regurgitation due to the poor quality color flow images. No reasonable RJA could be obtained in either the apical four chamber or two chamber views. Most of the supposed regurgitant jet appeared to be artifactual due to significantly inappropriate color gain and inappropriately low Nyquist limit. I

> digitized the apical views. I determined that the LAA in the apical four chamber view was 23.2 cm2. The LAA in the apical two chamber view was 25.1 cm2. The sonographer measured supposed RJAs of 7.10 cm2 and 6.15 cm2 in the apical four chamber view. The sonographer also measured supposed RJAs of 7.71 cm2 and 6.27 cm2 in the apical two chamber view. However, all of these measurements were completely inaccurate due to the inappropriate acquisition of these images. Without question, these supposed RJA determinations contained low velocity and non-mitral regurgitant flow. In addition, the still frame image provided by the Claimant also demonstrated low velocity and non-mitral regurgitant flow. The correct RJA could not be determined in the apical views. The supposed RJA measurements documented by Dr. Rosenthal and Dr. Dlabal in their Declarations are the same inaccurate measurements provided by the sonographer on the DVD.
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> ....
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> ... [T]here is no reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a. That is, the echocardiogram of September 29, 2002 was of poor quality and an accurate RJA could not be determined. Visually, taking into consideration the below standard performance of this study, mild mitral regurgitation was suggested. An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account the issue of inter-reader variability when the poor quality of the study is taken into consideration.

In response to the Technical Advisor Report, claimant argues that the Technical Advisor failed to apply the reasonable medical basis standard and instead "substituted his own non-objective opinions." Claimant also contends that the Technical Advisor did not provide conclusive evidence that the

level of mitral regurgitation was less than moderate because he, unlike claimant's physicians and the auditing cardiologist, could not provide an accurate measurement of the RJA. Instead, claimant says, Dr. Vigilante merely determined that Mr. Venetz's mitral regurgitation was "most likely mild."[15]

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. The Settlement Agreement requires that a claim for Level V Matrix Benefits be reduced to the B Matrix if the claimant had mild mitral regurgitation diagnosed by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period. See Settlement Agreement § IV.B.2.d.(2)(a).

Claimant contends that the opinions of Dr. Rosenthal and Dr. Dlabal establish a reasonable medical basis for Dr. Rosenthal's representation that claimant's September 29, 2002 echocardiogram demonstrates moderate mitral regurgitation. We disagree. We are required to apply the standards delineated in the Settlement Agreement and the Audit Policies and Procedures. The context of these two documents leads us to interpret the reasonable medical basis standard as more stringent than claimant contends and one that must be applied on a case-by-case basis.

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15. In addition, claimant argues that accepting Dr. Irani's RJA measurement of 5.4 cm^2 and Dr. Vigilante's LAA measurement of 23.2 cm^2 results in an RJA/LAA ratio of 23%, which qualifies for moderate mitral regurgitation. This ignores, again, however, Dr. Irani's statement that this measurement "do[es] not reflect the actual degree of mitral regurgitation and do[es] not reasonably support a finding of moderate mitral regurgitation."

For example, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See Mem. in Supp. of PTO No. 2640, at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

Here, Dr. Irani determined in audit that Mr. Venetz's level of regurgitation was inflated "due to inclusion of low velocity nonturbulent flow" and a "quite low" Nyquist limit.[16] Although claimant submitted declarations from Dr. Rosenthal and Dr. Dlabal, wherein they disputed Dr. Irani's conclusions in audit, Dr. Irani reviewed the echocardiogram again, including "those points identified by Drs. Rosenthal and Dlabal," and determined that "these still frames do not reflect the actual degree of mitral regurgitation and do not reasonably support a finding of moderate mitral regurgitation." Claimant submitted supplemental declarations from Dr. Rosenthal and Dr. Dlabal,

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16. Notably, claimant's expert, Dr. Dlabal, also acknowledged that "[t]he Nyquist Limit on this study is set at a somewhat low level."

wherein they disputed Dr. Irani's determinations, stating, instead, that the jets they measured constituted only turbulent flow and were representative of the mitral regurgitation seen in real time.

Dr. Vigilante subsequently reviewed claimant's echocardiogram and concluded that it "was performed significantly below the appropriate standard of care" as the Nyquist limit was "inappropriately" low and there "was significantly increased color gain." Dr. Vigilante explained that, while these limitations prevented him from obtaining an actual RJA measurement, he was able to determine that "[m]ost of the supposed regurgitant jet appeared to be artifactual due to significantly inappropriate color gain and inappropriately low Nyquist limit." In addition, Dr. Vigilante specifically reviewed the sonographer-determined measurements and determined that "all of these measurements were completely inaccurate." Importantly, Dr. Vigilante observed that "[t]he supposed RJA measurements documented by Dr. Rosenthal and Dr. Dlabal in their Declarations are the same inaccurate measurements provided by the sonographer on the DVD."[17] Such unacceptable practices cannot provide a reasonable medical basis for the resulting Green Form representation of moderate mitral regurgitation. To conclude otherwise would allow claimants who do not have moderate or

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17. For these reasons as well, we reject claimant's various challenges to the auditing cardiologist's and Technical Advisor's respective reviews.

greater mitral regurgitation to receive Matrix A-1 Benefits, which would be contrary to the intent of the Settlement Agreement.

We also reject claimant's assertion that he is entitled to Matrix A-1, Level V benefits under the Seventh Amendment. As an initial matter, the Seventh Amendment specifically states that "the determinations and actions of the Fund Administrator on any aspect of the claim of a Category One Class Member shall have no preclusive or precedential effect of any kind on the Trust in the administration ... of claims for Seventh Amendment Matrix Compensation Benefits."[18] Seventh Amendment § IX.E. The Seventh Amendment further provides that:

> For each Category One Class Member or Category Two Class Member found to be eligible for Seventh Amendment Matrix Compensation Benefits, the Trust shall calculate as a Net Matrix Amount, a sum equal to the gross amount payable to the Diet Drug Recipient or Representative Claimant and their associated Derivative Claimants, if any, on the applicable Matrix under section IV.B.2 of the Settlement Agreement ....

Id. § IX.A.2. (emphasis added). Section IV.B.2.d. sets forth "[t]he circumstances which determine whether Matrix A-1 or Matrix B-1 is applicable ...." Settlement Agreement § IV.B.2.d. As Mr.

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18. Under the Seventh Amendment, Seventh Amendment Matrix Compensation Benefits means "those Matrix Compensation Benefits which may be paid or claimed for High Matrix Level Qualifying Factors to or by Category One Class Members or Category Two Class Members in accordance with the terms of the Seventh Amendment." Seventh Amendment § I.64. Mr. Venetz's claim for Level V Matrix Benefits is a claim for Seventh Amendment Matrix Compensation Benefits.

Venetz failed to establish a reasonable medical basis for finding that he was not diagnosed "as having Mild Mitral Regurgitation by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period," id. § IV.B.2.d.(2)(a), the Settlement Agreement and the Seventh Amendment require his claim for Level V benefits to be reduced to Matrix B-1.

Therefore, we will affirm the Trust's denial of Mr. Venetz's claim for Matrix A-1 benefits, and the related derivative claim submitted by his spouse.